38. The method of claim 22 further comprising entirely subcutan ously implanting the catheter.

39. The method of claim 34 further comprising entirely subcutaneously implanting said catheter.

40. The method of claim 34 further comprising implanting said catheter in a breast and entirely subcutaneously implanting the catheter.

REMARKS

This Amendment is responsive to the Office Action of May 31, 2002. Claims 5, 12-14, and 20 have been canceled. Claims 1, 6, 10, 19, 22, and 33-34 have been amended. Claims 37-40 have been added. Claims 1-4, 6-11, 15-19, and 21-40 are pending in this case. Reconsideration is respectfully requested.

GENERALLY

The Examiner is thanked for his thorough examination and written explanation in the action. Applicants have amended the claims in view of the Examiner's helpful, written comments.

However, Applicants hold that neither Dietrich et al. nor Chen et al. properly disclose or teach a "self healing" membrane. Firstly, the catheter of Dietrich is not

intended to be implanted subcutaneously. Secondly, Chen et al. have the embodiment of FIGS. 2A and 2B in which the catheter is to be implanted subcutaneously, but without any piercing of the skin for access to the catheter. Thirdly, Chen et al. have an embodiment shown in FIG. 2C that has the catheter permanently protruding from a hole in the skin. That is, the device is not entirely subcutaneous, but has the proximal end of the catheter always protruding from the skin. In the first and second cases, there is no need for a self healing membrane because there is no piercing access. In the third case, there is no need for a self healing membrane because the catheter extends completely out through the skin and has an access opening at a proximal end that does not need to be sealed against seepage of body fluids. Therefore, there is no motivation in either reference to add the self healing membrane to any of the devices of the references. Therefore claims 1 and 6 are considered to be allowable over the art of record.

The funnel shape of the insert coupled at the proximal end of the subcutaneous catheter is not shown or taught by either Dietrich et al. or Chen et al. Specifically, the device of Dietrich et al. is not a subcutaneous catheter. Furthermore, the funnel shape is not a mere matter of design, but is for particular purposes that are claimed and disclosed. Indeed Claim 10 recites a means and a function not met by the art of record. Therefore, Claim 10 is considered to be allowable over the art relied upon.

Remote placement of a subcutaneous optical coupler is not shown or taught by either of Dietrich et al. or Chen et al. Chen et al. teach a remote optical coupler that is located outside the body of the patient and has a permanent transdermal catheter. Therefore, Claim 19 is considered to be allowable of the art of record.

The method of treatment including locating a catheter completely subderminally and in which the catheter includes a self healing membrane for sealing it against influx of body fluids as now claimed in claim 22 is not provided for by Dietrich et al. or Chen et al. singly or in combination. Similar to above arguments, the method including remote placement of an optical coupler at a remote position under the patient's skin as recited in Claim 34 is also not shown or taught by Dietrich et al. or Chen et al.

Amendments have been made to place these features in independent Claims 1, 6, 10, 19, 22, and 34.

If it appears that any further changes are needed, Applicants invite the Examiner to telephone the undersigned agent.

CLAIM REJECTIONS – CLAIMS – §112

Claims 12-15, 20, and 21 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants have cancelled Claims 12-14 and 20, and included similar matter in Claims 37-40 of the groupings of method Claims 22-40 where the functional aspects are recited as significant steps in the method of treatment. Therefore, the indefinite matter of Claims 12-14 has been removed from the claims.

Regarding Claim 15 the ambulatory laser and control circuit 54 are shown for example in Fig. 3. What these elements comprise is described on page 20 lines 18-23. Simply stated, Claim 15 seeks coverage of a portable laser and associated circuitry that are carried by the patient in a harness or belt 56 to facilitate low dosage and many repetitions of PDT. This feature finds support in the Description and the Figures as set forth above.

Regarding Claim 21, the transdermal optical connector is d scribed on page 22, lines 9-19, and exemplified at 68 in FIG. 6. Clarity is provided in that the pr fix "trans" means through or passing through, and the dermal means of or relating to the skin. Hence, an optical connector that passes through the skin.

Applicants respectfully submit that in light of these arguments, Claim 15 and 21 are clear and should not be subject to the rejection under USC §112, 2nd.

CLAIM REJECTIONS – CLAIMS 1-4, 6, 8, 10, 13-14, 19-23, 27-28, and 33 – §102(b)

Claims 1-4, 6, 8, 10, 13-14, 19-23, 27-28, and 33 were rejected under 35 U.S.C. 102(b) as being anticipated by Dietrich et al. (US 4,612,938). This rejection is respectfully traversed.

The device and method of Dietrich et al. is specifically for treatment of cancer on inner walls of a patient's bladder. Hence, the device of Dietrich et al. is not the same as one that can be placed subcutaneously like the instant invention. One needed feature for such placement is lacking in Dietrich et al. That is, the self healing membrane that is now recited in claims 1and 6.

Claim 10 has been made independent and recites the funnel shape of the insert as well as the inflatable balloon. Dietrich et al. do not have the inflatable balloon in the same embodiment that has a funnel end. Furthermore, Dietrich does not have an insert at all since the funnel shaped member in FIG. 1 appears to be unitarily formed with the catheter. Aside from these arguments, it should be noted that the funnel shaped member of the instant invention serves for different purposes from those of Dietrich et al. One of the purposes for this funnel shape is for making insertion under the skin of the patient

easier, which is not taught or shown by Dietrich. In this way, the instant Claim 10 recites a means plus function that is not provided by Dietrich et al. Therefore, Claim 10 is considered to be allowable over Dietrich et al.

Claim 19 has been amended to be independent and includes a subdermally implanted remote optical coupler. Dietrich et al. do not teach a remote coupler implanted subderminally in the patient. This feature is advantageous for convenience of location of an access prot for repeated treatments. Furthermore, this feature has the advantage of locating transdermal openings remote from the site of the tumor resection. In this way the chances of infections in the resection area are reduced. These advantages are not taught by Dietrich et al. Therefore, Claim 19 is distinct from and non-obvious over Dietrich et al.

Regarding claim 22, Dietrich et al. do not teach complete subcutaneous imbedding of their device including proximal and distal ends of the device as now recited.

Claim 34 now includes the matter of original Claims 22 and 33. As such, Claim 34 now recites the method of treatment including locating a remote access port subcutaneously in the patient. This step is not taught by Dietrich et al.

Applicants respectfully submit that independent Claims 1, 6, 10, 19, 22, and 34 are allowable over Dietrich et al. Applicants further submit that dependent Claims 2-4, 7-9, 11, 15-18, 21, 23-33, and 35-40 are allowable since they depend from allowable base claims, for additional patentable features recited therein, and for further grounds as may be recognized by the Examiner.

CLAIM REJECTIONS – CLAIMS 5, 7, 9, 11, 15-17, 24-26, 29-31, and 34-36 – §103(a)

Claims 5, 7, 9, 11, 15-17, 24-26, 29-31, and 34-36 were r jected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al. (US 4,612,938) in view of Chen et al. (US 5,445,608). This rejection is respectfully traversed.

It appears form the Examiner's rejection on page 3, lines 5-7 that the Examiner has misunderstood the purpose of the plug and the self sealing membrane of the instant invention. Furthermore, the non-existent self sealing membrane applied to the art relied upon and the plug (not explicitly identified) are not needed for sealing the fluid in the balloon as characterized in lines 5-7 of page 3 by the Examiner. It is believed that the fluids are sealed in the balloons of Dietrich et al. and Chen et al. by conventional means. The instant invention also seals the fluid in the balloon by a valve. The plug and self healing membrane of the instant invention are for sealing the overall device against entry of body fluids so that an optic fiber can be passed through the skin and the self healing membrane in a manner that prevents body fluids from entering the overall catheter. Neither of Dietrich et al. or Chen et al. have any disclosure of piercing the skin and a self healing membrane and threading of an optical fiber through the skin and the self healing membrane in accordance with the instant invention.

Claim 5 has been canceled. However, the matter of claim 5 has been incorporated into Claim 1. Applicants argue that the rejection of Claim 5 was improper since neither Dietrich et al. nor Chen et al. have a self healing membrane. Firstly, the catheter of Dietrich is not intended to be implanted subcutaneously. Secondly, Chen et al. have the embodiment of FIGS. 2A and 2B in which the catheter is to be implanted subcutaneously, but without any piercing of the skin for access to the catheter. Thirdly, Chen et al. have an

embodiment shown in FIG. 2C that has the catheter permanently protruding from a hole in the skin. That is, the device is not entirely subcutaneous, but has the proximal end of the catheter always protruding from the skin. In the first and second cases, there is no need for a self healing membrane because there is no piercing access. In the third case, there is no need for a self healing membrane because the catheter extends completely out through the skin and has an access opening at a proximal end that does not need to be sealed against seepage of body fluids. Therefore, there is no motivation in either reference to add the self healing membrane to any of the devices of the references. Therefore Claim 1 (incorporating original Claim 5) is considered to be allowable over the art of record.

For these reasons, Applicants respectfully submit that independent Claim 1 as amended is allowable over Dietrich et al. and Chen et al. Applicants further submit that dependent Claims 7, 9, 11, 15-17, 24-26, 29-31, and 34-36 are allowable since they depend from allowable base claims, for additional patentable features recited therein, and for further grounds as may be recognized by the Examiner.

CLAIM REJECTIONS – CLAIMS 18 and 32 – §103(a)

Claims 18 and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al. (US 4,612,938) and Chen et al. (US 5,445,608) in further view of Hayman et al. (US. 5,267,960). This rejection is respectfully traversed.

Applicants respectfully submit that dependent Claims 18 and 32 are allowable over Dietrich et al. and Chen et al. in further view of Haymam et al. since they depend from

allowable base claims, for additional patentable features recited th rein, and for further grounds as may be recognized by the Examiner.

SUMMARY

Based on the above amendments and accompanying remarks, Applicants respectfully submit that all pending claims are in condition for allowance and earnestly solicits a notice thereof. Applicants encourage the Examiner to telephone the undersigned agent if it appears that a telephone conference would facilitate allowance of the application.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on

July 30, 2002

By Nancy McElrath

Signature

July 30, 2002

Respectfully submitted,

David E. Allred
Registration No. 47,254
Myers, Dawes & Andras LLP
19900 MacArthur Boulevard, Suite 1150
Irvine, CA 92612
(949) 223-9600

V rsion With Markings To Show Chang Mad

In the Claims:

1. An apparatus for placement in a body cavity having an inner surface in a patient, said apparatus comprising:

an implantable, inflatable balloon for disposition into said body cavity and which when inflated expands into said body cavity to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed to at least one point within an interior of said balloon; ~~and~~

a subcutaneous, implantable catheter coupled to said inflatable balloon for percutant disposition into said patient to access said body cavity, said catheter arranged and configured to provide repetitive access to said body cavity over an extended period of time, and having an first lumen to allow an optical fiber to be disposed through said first lumen into said inflatable balloon while being segregated from said interior of said balloon and to illuminate said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface, and having a second lumen for inflation of said balloon; and

wherein said subcutaneous catheter comprises a proximal end and a self-healing membrane coupled to and closing said proximal end..

6. An apparatus for placement in a body cavity having an inner surface in a patient, said apparatus comprising:

an implantable, inflatable balloon for disposition into said body cavity and which when inflated expands into said body cavity to allow substantially all of said inner surface to be exposed to at least one point within an interior of said balloon;

a subcutaneous, implantable catheter coupled to said inflatable balloon for percutant disposition into said patient to access said body cavity, said catheter arranged and configured to provide repetitive access to said body cavity over an extended period of time, and having a first lumen to allow an optical fiber to be disposed through said first lumen into said inflatable balloon while being segregated from said interior of said balloon and to illuminate said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface, and having a second lumen for inflation of said balloon; and

~~The apparatus of claim 1~~ wherein said subcutaneous catheter comprises a proximal end and comprises an insert removably coupled to said proximal end, said insert having a distal end removably coupled to said first lumen in said subcutaneous catheter and a self healing membrane supported in a proximal end of said insert, said self healing membrane sealingly closing the proximal insert for placement subcutaneously.

10. An apparatus for placement in a body cavity having an inner surface in a patient, said apparatus comprising:

an implantable, inflatable balloon for disposition into said body cavity and which when inflated expands into said body cavity to prevent said inner surface of said body

cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed to at least one point within an interior of said balloon; and

a subcutaneous, implantable catheter coupled to said inflatable balloon for percutant disposition into said patient to access said body cavity, said catheter arranged and configured to provide repetitive access to said body cavity over an extended period of time, and having an first lumen to allow an optical fiber to be disposed through said first lumen into said inflatable balloon while being segregated from said interior of said balloon and to illuminate said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface, and having a second lumen for inflation of said balloon; and, wherein:

said subcutaneous catheter comprises a proximal end and an insert coupled to said proximal end, ~~The apparatus of claim 6 wherein~~

said insert is funnel shaped, said insert has a distal end coupled to said first lumen in said subcutaneous catheter and said funnel shape of said insert narrows~~ing~~ down to where said insert is coupled to said lumen to ease in disposition of said insert into said patient and to facilitate introduction of said optical fiber therethrough without damage to said optical fiber.

19. An apparatus for placement in a body cavity having an inner surface in a patient, said apparatus comprising:

an implantable, inflatable balloon for disposition into said body cavity and which when inflated expands into said body cavity to prevent said inner surface of said body

cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed to at least one point within an interior of said balloon;

a subcutaneous, implantable catheter coupled to said inflatable balloon for percutant disposition into said patient to access said body cavity, said catheter arranged and configured to provide repetitive access to said body cavity over an extended period of time, and having a first lumen to allow an optical fiber to be disposed through said first lumen into said inflatable balloon while being segregated from said interior of said balloon and to illuminate said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface, and having a second lumen for inflation of said balloon; and

~~The apparatus of claim 1 further comprising~~ a subdermally implanted remote optical coupler and a permanently implanted optical fiber communicating between said optical coupler and said balloon.

22. A method of photodynamically treating a tumor resection characterized by a body cavity having an inner surface in a patient comprising:

selectively disposing and retaining a photosensitizing drug in cancerous tissue within said inner surface of said body cavity and adjacent thereto;

closing off a proximal end of a subcutaneous catheter by a self sealing membrane;

implanting said subcutaneous catheter so that both of a distal end and said proximal end are under the skin of the patient; wherein said step of implanting comprises

disposing an inflatable balloon coupled to said distal end of said subcutaneous catheter into said body cavity ~~coupled to a subcutaneous catheter~~;

inflating said inflatable balloon in said body cavity by means of a first lumen defined in said subcutaneous catheter to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed to at least one point within said balloon;

disposing an optical fiber through a second lumen defined in said subcutaneous catheter to position a distal end of said optical fiber within said inflatable balloon; and

repetitively delivering a fractionated dosage of light through said optical fiber to effectively photodynamically treat said tumor resection by repetitively piercing the self sealing membrane in order to pass said distal end of said optical fiber through to said distal end of the subcutaneous catheter.

33. The method of claim 22, further comprising providing a remote access port by implanting said proximal end of the subcutaneous catheter at a position remote from skin covering said recess, wherein disposing said optical fiber through said subcutaneous catheter comprises disposing said optical fiber through ~~an~~ said implanted remote access port.

34. A method of photodynamically treating a tumor resection characterized by a body cavity having an inner surface in a patient comprising:

selectively disposing and retaining a photosensitizing drug in cancerous tissue within said inner surface of said body cavity and adjacent thereto;

disposing an inflatable balloon into said body cavity coupled to a subcutaneous catheter;

inflating said inflatable balloon in said body cavity by means of a first lumen defined in said subcutaneous catheter to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed to at least one point within said balloon;

disposing an optical fiber through a second lumen defined in said subcutaneous catheter to position a distal end of said optical fiber within said inflatable balloon; and

repetitively delivering a fractionated dosage of light through said optical fiber to effectively photodynamically treat said tumor resection;

where disposing said optical fiber through said subcutaneous catheter comprises disposing said optical fiber through an implanted remote access port.

~~The method of claim 33~~ wherein disposing said optical fiber through a remote access port disposes said optical fiber to an optical coupler serving as said remote access port and having a permanent implanted optical fiber coupling said optical coupler to a light emission point positioned in said balloon, and where repetitively delivering a fractionated dosage of light through said optical fiber comprises coupling an external optical fiber to said optical coupler and delivering said fractionated dosage of light through said external optical fiber to said optical coupler.

37. The method of claim 22, wherein the catheter has a proximal end, and an insert is coupled to said proximal end; the method further comprising:

disposing said insert into a cranium and supporing said insert only by said cranium of said patient; and

supporting said insert by said cranium so that forces applied to said insert are prevented from being transmitted to underlying brain tissue.

38. The method of claim 22 further comprising entirely subcutaneously implanting the catheter.

39. The method of claim 34 further comprising entirely subcutaneously implanting said catheter.

40. The method of claim 34 further comprising implanting said catheter in a breast and entirely subcutaneously implanting the catheter.